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 MERCK SHARP & DOHME, CORP.

UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA
 Southern Division

MARY GANN, an individual

Plaintiff,

vs.

MERCK SHARP AND DOHME,
 CORP., et al.,

Defendants.

Case No.: SACV13-01403 AG (ANx)

DEFENDANT MERCK SHARP &
 DOHME CORP.'S ANSWER TO
 COMPLAINT AND AFFIRMATIVE
 DEFENSES

DEMAND FOR JURY TRIAL

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Defendant Merck Sharp & Dohme Corp. ("Merck"), by and through its undersigned attorneys, hereby answers those allegations of Plaintiff's Complaint ("Complaint") directed to it. Merck denies all allegations set forth in the Complaint directed at Merck except to the extent such allegations are specifically admitted below. To the extent the allegations of any paragraph are directed to other defendants and Does 1 through 10, Merck is not required to respond to those allegations. To the extent a response is deemed necessary, Merck is without knowledge or information sufficient to form a belief as to such allegations and therefore the allegations are denied.

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 1.

2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 2.

3. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 3.

4. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 4.

5. Merck denies each and every allegation of Paragraph 5, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

6. Merck denies each and every allegation of Paragraph 6, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

7. Merck denies each and every allegation of Paragraph 7, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

8. Merck denies each and every allegation of Paragraph 8, except that Merck admits that it is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business located at One Merck Drive, Whitehouse

1 Station, New Jersey 08889, and states that it is registered to do business in the State of
2 California.

3 9. Merck denies each and every allegation of Paragraph 9, except that Merck
4 admits that it is a corporation organized and existing under the laws of the State of New
5 Jersey with its principal place of business located at One Merck Drive, Whitehouse
6 Station, New Jersey 08889, and states that it is registered to do business in the State of
7 California.

8 10. The allegations of Paragraph 10 do not require a response.

9 11. Merck denies each and every allegation of Paragraph 11, except that it
10 admits that Merck manufactured, marketed, and distributed the prescription medicine
11 FOSAMAX® for prescription in accordance with its approved prescribing information.

12 12. Merck denies each and every allegation of Paragraph 12, except that it
13 admits that it is registered to do business in the State of California.

14 13. Merck is without knowledge as to what is meant by the phrase “derived
15 substantial revenue,” so the allegations of Paragraph 13 are denied.

16 14. Merck is without knowledge as to what is meant by the phrase “would
17 have consequences,” so the allegations of Paragraph 14 are denied.

18 15. The allegations of Paragraph 15 are directed to a defendant other than
19 Merck, and therefore Merck is not required to respond to those allegations. To the
20 extent a response is required, Merck states that it is without knowledge or information
21 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 15 and
22 therefore those allegations are denied.

23 16. The allegations of Paragraph 16 are directed to a defendant other than
24 Merck, and therefore Merck is not required to respond to those allegations. To the
25 extent a response is required, Merck states that it is without knowledge or information
26 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 16 and
27 therefore those allegations are denied.
28

1 17. The allegations of Paragraph 17 are directed to a defendant other than
2 Merck, and therefore Merck is not required to respond to those allegations. To the
3 extent a response is required, Merck states that it is without knowledge or information
4 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 17 and
5 therefore those allegations are denied.

6 18. The allegations of Paragraph 18 are directed to a defendant other than
7 Merck, and therefore Merck is not required to respond to those allegations. To the
8 extent a response is required, Merck states that it is without knowledge or information
9 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 18 and
10 therefore those allegations are denied.

11 19. The allegations of Paragraph 19 are directed to a defendant other than
12 Merck, and therefore Merck is not required to respond to those allegations. To the
13 extent a response is required, Merck states that it is without knowledge or information
14 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 19 and
15 therefore those allegations are denied.

16 20. The allegations of Paragraph 20 are directed to a defendant other than
17 Merck, and therefore Merck is not required to respond to those allegations. To the
18 extent a response is required, Merck states that it is without knowledge or information
19 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 20 and
20 therefore those allegations are denied.

21 21. The allegations of Paragraph 21 are directed to a defendant other than
22 Merck, and therefore Merck is not required to respond to those allegations. To the
23 extent a response is required, Merck states that it is without knowledge or information
24 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 21 and
25 therefore those allegations are denied.

26 22. The allegations of Paragraph 22 are directed to a defendant other than
27 Merck, and therefore Merck is not required to respond to those allegations. To the
28 extent a response is required, Merck states that it is without knowledge or information

1 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 22 and
2 therefore those allegations are denied.

3 23. The allegations of Paragraph 23 are directed to a defendant other than
4 Merck, and therefore Merck is not required to respond to those allegations. To the
5 extent a response is required, Merck states that it is without knowledge or information
6 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 23 and
7 therefore those allegations are denied.

8 24. The allegations of Paragraph 24 are directed to a defendant other than
9 Merck, and therefore Merck is not required to respond to those allegations. To the
10 extent a response is required, Merck states that it is without knowledge or information
11 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 24 and
12 therefore those allegations are denied.

13 25. The allegations of Paragraph 25 are directed to a defendant other than
14 Merck, and therefore Merck is not required to respond to those allegations. To the
15 extent a response is required, Merck states that it is without knowledge or information
16 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 25 and
17 therefore those allegations are denied.

18 26. The allegations of Paragraph 26 are directed to a defendant other than
19 Merck, and therefore Merck is not required to respond to those allegations. To the
20 extent a response is required, Merck states that it is without knowledge or information
21 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 26 and
22 therefore those allegations are denied.

23 27. The allegations of Paragraph 27 are directed to a defendant other than
24 Merck, and therefore Merck is not required to respond to those allegations. To the
25 extent a response is required, Merck states that it is without knowledge or information
26 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 27 and
27 therefore those allegations are denied.

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1 28. The allegations of Paragraph 28 are directed to a defendant other than
2 Merck, and therefore Merck is not required to respond to those allegations. To the
3 extent a response is required, Merck states that it is without knowledge or information
4 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 28 and
5 therefore those allegations are denied.

6 29. The allegations of Paragraph 29 are directed to a defendant other than
7 Merck, and therefore Merck is not required to respond to those allegations. To the
8 extent a response is required, Merck states that it is without knowledge or information
9 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 29 and
10 therefore those allegations are denied.

11 30. The allegations of Paragraph 30 are directed to a defendant other than
12 Merck, and therefore Merck is not required to respond to those allegations. To the
13 extent a response is required, Merck states that it is without knowledge or information
14 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 30 and
15 therefore those allegations are denied.

16 31. The allegations of Paragraph 31 are directed to a defendant other than
17 Merck, and therefore Merck is not required to respond to those allegations. To the
18 extent a response is required, Merck states that it is without knowledge or information
19 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 31 and
20 therefore those allegations are denied.

21 32. The allegations of Paragraph 32 are directed to a defendant other than
22 Merck, and therefore Merck is not required to respond to those allegations. To the
23 extent a response is required, Merck states that it is without knowledge or information
24 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 32 and
25 therefore those allegations are denied.

26 33. The allegations of Paragraph 33 are directed to a defendant other than
27 Merck, and therefore Merck is not required to respond to those allegations. To the
28 extent a response is required, Merck states that it is without knowledge or information

1 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 33 and
2 therefore those allegations are denied.

3 34. The allegations of Paragraph 34 are directed to a defendant other than
4 Merck, and therefore Merck is not required to respond to those allegations. To the
5 extent a response is required, Merck states that it is without knowledge or information
6 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 34 and
7 therefore those allegations are denied.

8 35. The allegations of Paragraph 35 are directed to a defendant other than
9 Merck, and therefore Merck is not required to respond to those allegations. To the
10 extent a response is required, Merck states that it is without knowledge or information
11 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 35 and
12 therefore those allegations are denied.

13 36. The allegations of Paragraph 36 are directed to a defendant other than
14 Merck, and therefore Merck is not required to respond to those allegations. To the
15 extent a response is required, Merck states that it is without knowledge or information
16 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 36 and
17 therefore those allegations are denied.

18 37. The allegations of Paragraph 37 are directed to a defendant other than
19 Merck, and therefore Merck is not required to respond to those allegations. To the
20 extent a response is required, Merck states that it is without knowledge or information
21 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 37 and
22 therefore those allegations are denied.

23 38. The allegations of Paragraph 38 are directed to a defendant other than
24 Merck, and therefore Merck is not required to respond to those allegations. To the
25 extent a response is required, Merck states that it is without knowledge or information
26 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 38 and
27 therefore those allegations are denied.
28

1 39. The allegations of Paragraph 39 are directed to a defendant other than
2 Merck, and therefore Merck is not required to respond to those allegations. To the
3 extent a response is required, Merck states that it is without knowledge or information
4 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 39 and
5 therefore those allegations are denied.

6 40. The allegations of Paragraph 40 are directed to a defendant other than
7 Merck, and therefore Merck is not required to respond to those allegations. To the
8 extent a response is required, Merck states that it is without knowledge or information
9 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 40 and
10 therefore those allegations are denied.

11 41. The allegations of Paragraph 41 are directed to a defendant other than
12 Merck, and therefore Merck is not required to respond to those allegations. To the
13 extent a response is required, Merck states that it is without knowledge or information
14 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 41 and
15 therefore those allegations are denied.

16 42. The allegations of Paragraph 42 are directed to a defendant other than
17 Merck, and therefore Merck is not required to respond to those allegations. To the
18 extent a response is required, Merck states that it is without knowledge or information
19 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 42 and
20 therefore those allegations are denied.

21 43. The allegations of Paragraph 43 are directed to a defendant other than
22 Merck, and therefore Merck is not required to respond to those allegations. To the
23 extent a response is required, Merck states that it is without knowledge or information
24 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 43 and
25 therefore those allegations are denied.

26 44. The allegations of Paragraph 44 are directed to a defendant other than
27 Merck, and therefore Merck is not required to respond to those allegations. To the
28 extent a response is required, Merck states that it is without knowledge or information

1 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 44 and
2 therefore those allegations are denied.

3 45. The allegations of Paragraph 45 are directed to a defendant other than
4 Merck, and therefore Merck is not required to respond to those allegations. To the
5 extent a response is required, Merck states that it is without knowledge or information
6 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 45 and
7 therefore those allegations are denied.

8 46. The allegations of Paragraph 46 are directed to a defendant other than
9 Merck, and therefore Merck is not required to respond to those allegations. To the
10 extent a response is required, Merck states that it is without knowledge or information
11 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 46 and
12 therefore those allegations are denied.

13 47. The allegations of Paragraph 47 are directed to a defendant other than
14 Merck, and therefore Merck is not required to respond to those allegations. To the
15 extent a response is required, Merck states that it is without knowledge or information
16 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 47 and
17 therefore those allegations are denied.

18 48. The allegations of Paragraph 48 are directed to a defendant other than
19 Merck, and therefore Merck is not required to respond to those allegations. To the
20 extent a response is required, Merck states that it is without knowledge or information
21 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 48 and
22 therefore those allegations are denied.

23 49. The allegations of Paragraph 49 are directed to a defendant other than
24 Merck, and therefore Merck is not required to respond to those allegations. To the
25 extent a response is required, Merck states that it is without knowledge or information
26 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 49 and
27 therefore those allegations are denied.

28

1 50. The allegations of Paragraph 50 are directed to a defendant other than
2 Merck, and therefore Merck is not required to respond to those allegations. To the
3 extent a response is required, Merck states that it is without knowledge or information
4 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 50 and
5 therefore those allegations are denied.

6 51. The allegations of Paragraph 51 are directed to a defendant other than
7 Merck, and therefore Merck is not required to respond to those allegations. To the
8 extent a response is required, Merck states that it is without knowledge or information
9 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 51 and
10 therefore those allegations are denied.

11 52. The allegations of Paragraph 52 are directed to a defendant other than
12 Merck, and therefore Merck is not required to respond to those allegations. To the
13 extent a response is required, Merck states that it is without knowledge or information
14 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 52 and
15 therefore those allegations are denied.

16 53. The allegations of Paragraph 53 are directed to a defendant other than
17 Merck, and therefore Merck is not required to respond to those allegations. To the
18 extent a response is required, Merck states that it is without knowledge or information
19 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 53 and
20 therefore those allegations are denied.

21 54. The allegations of Paragraph 54 are directed to a defendant other than
22 Merck, and therefore Merck is not required to respond to those allegations. To the
23 extent a response is required, Merck states that it is without knowledge or information
24 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 54 and
25 therefore those allegations are denied.

26 55. The allegations of Paragraph 55 are directed to a defendant other than
27 Merck, and therefore Merck is not required to respond to those allegations. To the
28 extent a response is required, Merck states that it is without knowledge or information

1 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 55 and
2 therefore those allegations are denied.

3 56. The allegations of Paragraph 56 are directed to a defendant other than
4 Merck, and therefore Merck is not required to respond to those allegations. To the
5 extent a response is required, Merck states that it is without knowledge or information
6 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 56 and
7 therefore those allegations are denied.

8 57. The allegations of Paragraph 57 are directed to a defendant other than
9 Merck, and therefore Merck is not required to respond to those allegations. To the
10 extent a response is required, Merck states that it is without knowledge or information
11 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 57 and
12 therefore those allegations are denied.

13 58. The allegations of Paragraph 58 are directed to a defendant other than
14 Merck, and therefore Merck is not required to respond to those allegations. To the
15 extent a response is required, Merck states that it is without knowledge or information
16 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 58 and
17 therefore those allegations are denied.

18 59. The allegations of Paragraph 59 are directed to a defendant other than
19 Merck, and therefore Merck is not required to respond to those allegations. To the
20 extent a response is required, Merck states that it is without knowledge or information
21 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 59 and
22 therefore those allegations are denied.

23 60. The allegations of Paragraph 60 are directed to a defendant other than
24 Merck, and therefore Merck is not required to respond to those allegations. To the
25 extent a response is required, Merck states that it is without knowledge or information
26 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 60 and
27 therefore those allegations are denied.

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1 61. The allegations of Paragraph 61 are directed to a defendant other than
2 Merck, and therefore Merck is not required to respond to those allegations. To the
3 extent a response is required, Merck states that it is without knowledge or information
4 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 61 and
5 therefore those allegations are denied.

6 62. The allegations of Paragraph 62 are directed to a defendant other than
7 Merck, and therefore Merck is not required to respond to those allegations. To the
8 extent a response is required, Merck states that it is without knowledge or information
9 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 62 and
10 therefore those allegations are denied.

11 63. The allegations of Paragraph 63 are directed to a defendant other than
12 Merck, and therefore Merck is not required to respond to those allegations. To the
13 extent a response is required, Merck states that it is without knowledge or information
14 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 63 and
15 therefore those allegations are denied.

16 64. The allegations of Paragraph 64 are directed to a defendant other than
17 Merck, and therefore Merck is not required to respond to those allegations. To the
18 extent a response is required, Merck states that it is without knowledge or information
19 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 64 and
20 therefore those allegations are denied.

21 65. The allegations of Paragraph 65 are directed to a defendant other than
22 Merck, and therefore Merck is not required to respond to those allegations. To the
23 extent a response is required, Merck states that it is without knowledge or information
24 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 65 and
25 therefore those allegations are denied.

26 66. The allegations of Paragraph 66 are directed to a defendant other than
27 Merck, and therefore Merck is not required to respond to those allegations. To the
28 extent a response is required, Merck states that it is without knowledge or information

1 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 66 and
2 therefore those allegations are denied.

3 67. The allegations of Paragraph 67 are directed to a defendant other than
4 Merck, and therefore Merck is not required to respond to those allegations. To the
5 extent a response is required, Merck states that it is without knowledge or information
6 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 67 and
7 therefore those allegations are denied.

8 68. The allegations of Paragraph 68 are directed to a defendant other than
9 Merck, and therefore Merck is not required to respond to those allegations. To the
10 extent a response is required, Merck states that it is without knowledge or information
11 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 68 and
12 therefore those allegations are denied.

13 69. The allegations of Paragraph 69 are directed to a defendant other than
14 Merck, and therefore Merck is not required to respond to those allegations. To the
15 extent a response is required, Merck states that it is without knowledge or information
16 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 69 and
17 therefore those allegations are denied.

18 70. The allegations of Paragraph 70 are directed to a defendant other than
19 Merck, and therefore Merck is not required to respond to those allegations. To the
20 extent a response is required, Merck states that it is without knowledge or information
21 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 70 and
22 therefore those allegations are denied.

23 71. The allegations of Paragraph 71 are directed to a defendant other than
24 Merck, and therefore Merck is not required to respond to those allegations. To the
25 extent a response is required, Merck states that it is without knowledge or information
26 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 71 and
27 therefore those allegations are denied.

1 72. The allegations of Paragraph 72 are directed to a defendant other than
2 Merck, and therefore Merck is not required to respond to those allegations. To the
3 extent a response is required, Merck states that it is without knowledge or information
4 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 72 and
5 therefore those allegations are denied.

6 73. The allegations of Paragraph 73 are directed to a defendant other than
7 Merck, and therefore Merck is not required to respond to those allegations. To the
8 extent a response is required, Merck states that it is without knowledge or information
9 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 73 and
10 therefore those allegations are denied.

11 74. The allegations of Paragraph 74 are directed to a defendant other than
12 Merck, and therefore Merck is not required to respond to those allegations. To the
13 extent a response is required, Merck states that it is without knowledge or information
14 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 74 and
15 therefore those allegations are denied.

16 75. The allegations of Paragraph 75 are directed to a defendant other than
17 Merck, and therefore Merck is not required to respond to those allegations. To the
18 extent a response is required, Merck states that it is without knowledge or information
19 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 75 and
20 therefore those allegations are denied.

21 76. The allegations of Paragraph 76 are directed to a defendant other than
22 Merck, and therefore Merck is not required to respond to those allegations. To the
23 extent a response is required, Merck states that it is without knowledge or information
24 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 76 and
25 therefore those allegations are denied.

26 77. The allegations of Paragraph 77 are directed to a defendant other than
27 Merck, and therefore Merck is not required to respond to those allegations. To the
28 extent a response is required, Merck states that it is without knowledge or information

1 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 77 and
2 therefore those allegations are denied.

3 78. The allegations of Paragraph 78 are directed to a defendant other than
4 Merck, and therefore Merck is not required to respond to those allegations. To the
5 extent a response is required, Merck states that it is without knowledge or information
6 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 78 and
7 therefore those allegations are denied.

8 79. The allegations of Paragraph 79 are directed to a defendant other than
9 Merck, and therefore Merck is not required to respond to those allegations. To the
10 extent a response is required, Merck states that it is without knowledge or information
11 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 79 and
12 therefore those allegations are denied.

13 80. The allegations of Paragraph 80 are directed to a defendant other than
14 Merck, and therefore Merck is not required to respond to those allegations. To the
15 extent a response is required, Merck states that it is without knowledge or information
16 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 80 and
17 therefore those allegations are denied.

18 81. The allegations of Paragraph 81 are directed to a defendant other than
19 Merck, and therefore Merck is not required to respond to those allegations. To the
20 extent a response is required, Merck states that it is without knowledge or information
21 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 81 and
22 therefore those allegations are denied.

23 82. The allegations of Paragraph 82 are directed to a defendant other than
24 Merck, and therefore Merck is not required to respond to those allegations. To the
25 extent a response is required, Merck states that it is without knowledge or information
26 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 82 and
27 therefore those allegations are denied.
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1 83. The allegations of Paragraph 83 are directed to a defendant other than
2 Merck, and therefore Merck is not required to respond to those allegations. To the
3 extent a response is required, Merck states that it is without knowledge or information
4 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 83 and
5 therefore those allegations are denied.

6 84. The allegations of Paragraph 84 are directed to a defendant other than
7 Merck, and therefore Merck is not required to respond to those allegations. To the
8 extent a response is required, Merck states that it is without knowledge or information
9 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 84 and
10 therefore those allegations are denied.

11 85. The allegations of Paragraph 85 do not require a response.

12 86. Merck denies each and every allegation of Paragraph 86.

13 87. Merck denies each and every allegation of Paragraph 87.

14 88. Merck denies each and every allegation of Paragraph 88.

15 89. The allegations of Paragraph 89 are directed to a defendant other than
16 Merck, and therefore Merck is not required to respond to those allegations. To the
17 extent a response is required, Merck states that it is without knowledge or information
18 sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 89 and
19 therefore those allegations are denied.

20 90. Merck denies each and every allegation of Paragraph 90.

21 91. Merck denies each and every allegation of Paragraph 91.

22 92. Merck denies each and every allegation of Paragraph 92.

23 93. Merck denies each and every allegation of Paragraph 93.

24 94. Merck denies each and every allegation of Paragraph 94.

25 95. Merck denies each and every allegation of Paragraph 95.

26 96. Merck denies each and every allegation of Paragraph 96.

27 97. Merck lacks knowledge or information sufficient to form a belief as to the
28 truth or falsity of the allegations in Paragraph 97.

1 98. Merck denies each and every allegation of Paragraph 98.

2 99. Merck denies each and every allegation of Paragraph 99.

3 100. Merck denies each and every allegation of Paragraph 100.

4 **SUMMARY OF THE CASE**

5 101. Merck denies each and every allegation of Paragraph 101, except that
 6 Merck admits that it manufactured, marketed, and distributed the prescription medicine
 7 FOSAMAX® for prescription in accordance with its approved prescribing information,
 8 and admits that Merck has stated, consistent with the FDA approved prescribing
 9 information, that FOSAMAX® is indicated for the treatment of osteoporosis in post-
 10 menopausal women, as FOSAMAX® increases bone mass and reduces the incidence of
 11 fractures, including those of the hip and spine (vertebral compression fractures). Merck
 12 respectfully refers the Court to the Physician's Desk Reference ("PDR") for
 13 FOSAMAX® for its actual language and full text.

14 102. Merck denies each and every allegation of Paragraph 102, except that
 15 Merck admits that it manufactured, marketed, and distributed the prescription medicine
 16 FOSAMAX® for prescription in accordance with its approved prescribing information,
 17 and admits that Merck has stated, consistent with the FDA approved prescribing
 18 information, that FOSAMAX® is indicated for the treatment of osteoporosis in post-
 19 menopausal women, as FOSAMAX® increases bone mass and reduces the incidence of
 20 fractures, including those of the hip and spine (vertebral compression fractures).

21 103. Merck denies each and every allegation of Paragraph 103, except that
 22 Merck admits that it marketed the prescription medicine FOSAMAX® for prescription
 23 in accordance with its approved prescribing information, and that Alonso-Coello, et al.,
 24 published an article entitled *Drugs for Pre-osteoporosis: Prevention or Disease*
 25 *Mongering?*, British Med. J. 2008 Jan 19;336(7636):126-29, and respectfully refers the
 26 Court to said article for its actual language and full and complete text.

27 104. Merck denies each and every allegation of Paragraph 104.

1 105. Merck denies each and every allegation of Paragraph 105, except that
2 Merck admits only that the American Society for Bone and Mineral Research
3 (“ASBMR”) Task Force issued a report, which speaks for itself.

4 106. Merck denies each and every allegation of Paragraph 106, except that it
5 admits that Merck manufactured, marketed, and distributed the prescription medicine
6 FOSAMAX® for prescription in accordance with its approved prescribing information.

7 107. Merck denies each and every allegation of Paragraph 107, except that
8 Merck admits that FOSAMAX® product sales in 2008 amounted to approximately
9 \$1.55 billion and Merck is without knowledge as to whether Plaintiff used
10 FOSAMAX®. Merck denies the remaining allegations in Paragraph 107.

11 108. Merck denies each and every allegation of Paragraph 108, except that it
12 admits that Alonso-Coello, et al., published an article entitled *Drugs for Pre-*
13 *osteoporosis: Prevention or Disease Mongering?*, British Med. J. 2008 Jan
14 19;336(7636):126-29, and respectfully refers the Court to said article for its actual
15 language and full and complete text.

16 109. Merck denies each and every allegation of Paragraph 109.

17 110. Merck denies each and every allegation of Paragraph 110.

18 111. Merck denies each and every allegation of Paragraph 111, except Merck
19 admits that bone remodeling is a continuous process involving osteoclasts, osteoblasts,
20 and osteocytes, and that the rate of remodeling varies depending upon the skeletal site
21 and other factors.

22 112. Merck denies each and every allegation of Paragraph 112.

23 113. Merck denies each and every allegation of Paragraph 113, except that it
24 admits that BMD has been generally accepted in the medical community as a means by
25 which to diagnose osteoporosis.

26 114. Merck denies each and every allegation of Paragraph 114, except Merck
27 respectfully refers the Court to the prescribing information for FOSAMAX® for a more
28 complete description of the FDA approved Indications and Usage for FOSAMAX®.

Merck further admits that van der Meulen, et al., published an article entitled *Understanding bone strength: size isn't everything*, Bone. 2001 Aug. 29;29(2):101-4, Weinstein published an article entitled *True Strength*, Journal of Bone and Mineral Research, 2000;15(4):621-25, Burr published an article entitled *Microdamage and bone strength*, Osteoporos Int. 2003;14(Suppl. 5):S67-S72, and Unnanuntana, et al., published an article entitled *The Assessment of Fracture Risk*, J. Bone Joint Surg. Am. 2010;92:743-53. Merck respectfully refers the Court to said articles for their actual language and full and complete text.

115. Merck denies each and every allegation of Paragraph 115.

116. Merck denies each and every allegation of Paragraph 116, except that it admits that Shane E, Burr D, Ebeling PR, et al. published an article entitled *Atypical Subtrochanteric and Diaphyseal Femoral Fractures: Report of a Task Force of the American Society for Bone and Mineral Research*, J Bone Miner Res. 2010 Nov.; 25:2267-94, and respectfully refers the Court to said article for its actual language and full and complete text.

117. Merck denies each and every allegation of Paragraph 117, except that it admits that Ekstrom, et al., published an article entitled *Quality of life after a subtrochanteric fracture: a prospective cohort study on 87 elderly patients*, Injury 2009, 40:371-376, and Park-Wyllie, et al., published an article entitled *Bisphosphonate Use and the Risk of Subtrochanteric or Femoral Shaft Fractures in Older Women* in the Journal of the American Medical Association in February 2011. Merck respectfully refers the Court to said articles for their actual language and full and complete text.

118. Merck denies each and every allegation of Paragraph 118.

119. Merck denies each and every allegation of Paragraph 119, except that it admits that Isaacs, et al., published an article entitled *Femoral Insufficiency Fractures Associated with Prolonged Bisphosphonate Therapy*, Clin. Orthop. Relat. Res. (2010) 468:3384-3392, Neviaser, et al., published an article entitled *Low-Energy Femoral Shaft Fractures Associated with Alendronate Use*, J Orthop Trauma 2008 May-

1 Jun;22(5):346-50, Lenart, et al., published an article entitled *Association of Low-Energy*
 2 *Femoral Fractures With Prolonged Bisphosphonate Use: A Case Control Study*,
 3 *Osteoporos Int.* 2009 Aug;20(8):1353-62, Park-Wyllie, et al., published an article
 4 entitled *Bisphosphonate Use and the Risk of Subtrochanteric or Femoral Shaft*
 5 *Fractures in Older Women* in the *Journal of the American Medical Association* in
 6 February 2011, and Nieves, et al. published an article entitled *Fragility fractures of the*
 7 *hip and femur: incidence and patient characteristics*, *Osteoporos Int.* (2010) 21:399-
 8 408. Merck respectfully refers the Court to said articles for their actual language and
 9 full and complete text.

10 120. Merck denies each and every allegation of Paragraph 120, and states that
 11 the Merck documents referenced in Paragraph 120 speak for themselves.

12 121. Merck denies each and every allegation of Paragraph 121, and states that
 13 the Merck documents referenced in Paragraph 121 speak for themselves.

14 122. Merck denies each and every allegation of Paragraph 122, except that it
 15 admits that Berenson published an article entitled *Doctor Suggests Merck Trial May*
 16 *Have Led to Demotion*, THE NEW YORK TIMES, Dec. 10, 2005, and respectfully refers
 17 the Court to said article for its actual language and full and complete text.

18 123. Merck denies each and every allegation of Paragraph 123, and respectfully
 19 refers the Court to the FDA approved prescribing information for FOSAMAX® for the
 20 Warnings, Precautions, Contraindications and Adverse Reactions for the actual
 21 language and full and complete text, and denies each and every allegation of Paragraph
 22 123 that is inconsistent with the FDA approved prescribing information for
 23 FOSAMAX®.

24 124. Merck denies each and every allegation of Paragraph 124.

25 125. Merck denies each and every allegation of Paragraph 125, and respectfully
 26 refers the Court to the FDA approved prescribing information for FOSAMAX® for the
 27 Warnings, Precautions, Contraindications and Adverse Reactions for the actual
 28 language and full and complete text, and denies each and every allegation of Paragraph

1 125 that is inconsistent with the FDA approved prescribing information for
2 FOSAMAX®.

3 126. Merck denies each and every allegation of Paragraph 126, except admits
4 FDA Center for Drug Evaluation and Research held a joint meeting of the Advisory
5 Committee for Reproductive Health Drugs and Drug Safety and Risk Management
6 Advisory Committee on September 9, 2011, and Merck respectfully refers the Court to
7 the Transcript and Summary Minutes for said meeting for its actual language and full
8 and complete text.

9 127. Merck denies each and every allegation of Paragraph 127, except that it
10 admits that Jill U. Adams published an article entitled *Benefits of osteoporosis drugs*
11 *outweigh a risk, study says*, L.A. TIMES, May 29, 2011, and Park-Wyllie, et al.,
12 published an article entitled *Bisphosphonate Use and the Risk of Subtrochanteric or*
13 *Femoral Shaft Fractures in Older Women* in the Journal of the American Medical
14 Association in February 2011. Merck respectfully refers the Court to said articles for
15 their actual language and full and complete text.

16 128. Merck denies each and every allegation of Paragraph 128, except that it
17 admits that Merck has stated, consistent with the FDA approved prescribing
18 information, that FOSAMAX® is indicated for the treatment of osteoporosis in post-
19 menopausal women, as FOSAMAX® increases bone mass and reduces the incidence of
20 fractures, including those of the hip and spine (vertebral compression fractures). Merck
21 respectfully refers the Court to the prescribing information for FOSAMAX® for a more
22 complete description of the FDA approved Indications and Usage for FOSAMAX®.
23 Merck denies the remaining allegations of Paragraph 128.

24 129. Merck denies each and every allegation of Paragraph 129, and states that
25 the Merck documents referenced in Paragraph 129 speak for themselves.

26 130. Merck denies each and every allegation of Paragraph 130.

27 131. Merck denies each and every allegation of Paragraph 131.
28

132. Merck denies each and every allegation of Paragraph 132, except states that to the extent that the allegations of Paragraph 132 are conclusions of law, no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

133. Merck denies each and every allegation of Paragraph 133.

134. Merck denies each and every allegation of Paragraph 134.

135. Merck denies each and every allegation of Paragraph 135.

136. Merck denies each and every allegation of Paragraph 136.

137. Merck denies each and every allegation of Paragraph 137.

138. Merck denies each and every allegation of Paragraph 138, including each and every allegation contained in subparagraphs (a) through (f).

139. The allegations in Paragraph 139 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

140. Merck denies each and every allegation of Paragraph 140.

141. Merck denies each and every allegation of Paragraph 141.

142. Merck denies each and every allegation of Paragraph 142.

143. Merck denies each and every allegation of Paragraph 143.

144. Merck denies each and every allegation of Paragraph 144.

145. Merck denies each and every allegation of Paragraph 145.

146. Merck denies each and every allegation of Paragraph 146.

147. Merck denies each and every allegation of Paragraph 147.

148. Merck denies each and every allegation of Paragraph 148.

149. Merck denies each and every allegation of Paragraph 149.

150. Merck denies each and every allegation of Paragraph 150.

151. Merck denies each and every allegation of Paragraph 151.

152. Merck denies each and every allegation of Paragraph 152.

153. Merck denies each and every allegation of Paragraph 153.

154. The allegations in Paragraph 154 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

155. Merck denies each and every allegation of Paragraph 155, including each and every allegation contained in subparagraphs (a) through (g).

Name-Brand Defendants

156. Merck denies each and every allegation of Paragraph 156, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

157. Merck denies each and every allegation of Paragraph 157.

158. Merck denies each and every allegation of Paragraph 158, except that Merck admits that its patent for FOSAMAX® expired in or about February 2008.

159. The allegations in Paragraph 159 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

160. The allegations in Paragraph 160 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

161. Merck denies each and every allegation of Paragraph 161.

162. Merck denies each and every allegation of Paragraph 162.

163. Merck denies each and every allegation of Paragraph 163.

164. Merck denies each and every allegation of Paragraph 164.

165. Merck denies each and every allegation of Paragraph 165.

Generic Defendants

166. The allegations of Paragraph 166 are directed to a defendant other than Merck, and therefore Merck is not required to respond to those allegations. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 166 and therefore those allegations are denied.

167. The allegations of Paragraph 167 are directed to a defendant other than Merck, and therefore Merck is not required to respond to those allegations. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 167 and therefore those allegations are denied.

168. The allegations of Paragraph 168 are directed to a defendant other than Merck, and therefore Merck is not required to respond to those allegations. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 168 and therefore those allegations are denied.

169. The allegations of Paragraph 169 are directed to a defendant other than Merck, and therefore Merck is not required to respond to those allegations. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 169 and therefore those allegations are denied.

170. The allegations of Paragraph 170 are directed to a defendant other than Merck, and therefore Merck is not required to respond to those allegations. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 170 and therefore those allegations are denied.

171. Merck denies each and every allegation of Paragraph 171, including each and every allegation contained in subparagraphs (a) through (b).

172. The allegations of Paragraph 172 are directed to a defendant other than Merck, and therefore Merck is not required to respond to those allegations. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 172 and therefore those allegations are denied.

173. The allegations of Paragraph 173 are directed to a defendant other than Merck, and therefore Merck is not required to respond to those allegations. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 173 and therefore those allegations are denied.

174. Merck denies each and every allegation of Paragraph 174.

Allegations of Fact Regarding Plaintiff

175. Merck is without knowledge as to whether Plaintiff was prescribed or took FOSAMAX® or the reasons why Plaintiff allegedly was prescribed and took FOSAMAX®. Merck denies the remaining allegations in Paragraph 175.

176. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 176.

177. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 177.

178. Merck denies each and every allegation of Paragraph 178.

179. Merck denies each and every allegation of Paragraph 179.

180. Merck denies each and every allegation of Paragraph 180.

181. Merck denies each and every allegation of Paragraph 181.

Punitive Damages

182. Merck denies each and every allegation of Paragraph 182.

183. Merck denies each and every allegation of Paragraph 183.

184. Merck denies each and every allegation of Paragraph 184.

185. Merck denies each and every allegation of Paragraph 185.

186. Merck denies each and every allegation of Paragraph 186.

187. Merck denies each and every allegation of Paragraph 187.

Jurisdiction

188. Merck denies each and every allegation of Paragraph 188.

189. Merck denies each and every allegation of Paragraph 189.

FIRST CAUSE OF ACTION

STRICT LIABILITY IN TORT-FAILURE TO WARN

190. Merck repleads its answers to Paragraphs 1 through and including 189, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

191. Merck denies each and every allegation of Paragraph 191.

192. Merck denies each and every allegation of Paragraph 192.

193. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 193.

194. Merck denies each and every allegation of Paragraph 194.

SECOND CAUSE OF ACTION

STRICT LIABILITY IN TORT-DESIGN DEFECT

195. Merck repleads its answers to Paragraphs 1 through and including 194, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

196. Merck denies each and every allegation of Paragraph 196.

197. Merck denies each and every allegation of Paragraph 197.

198. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 198.

199. Merck denies each and every allegation of Paragraph 199.

THIRD CAUSE OF ACTION**NEGLIGENCE**

200. Merck repleads its answers to Paragraphs 1 through and including 199, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

201. Merck denies each and every allegation of Paragraph 201.

202. Merck denies each and every allegation of Paragraph 202.

203. Merck denies each and every allegation of Paragraph 203.

204. Merck denies each and every allegation of Paragraph 204.

205. Merck denies each and every allegation of Paragraph 205.

FOURTH CAUSE OF ACTION**BREACH OF IMPLIED WARRANTY**

206. Merck repleads its answers to Paragraphs 1 through and including 205, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

207. Merck denies each and every allegation of Paragraph 207, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

208. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 208.

209. Merck denies each and every allegation of Paragraph 209.

210. Merck denies each and every allegation of Paragraph 210.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

211. Merck repleads its answers to Paragraphs 1 through and including 210, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

212. Merck denies each and every allegation of Paragraph 212, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

213. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first sentence of Paragraph 213. Merck denies the remaining allegations of Paragraph 213.

214. Merck denies each and every allegation of Paragraph 214.

SIXTH CAUSE OF ACTION

DECEIT BY CONCEALMENT-CAL. CIVIL CODE §§ 1709, 1710

215. Merck repleads its answers to Paragraphs 1 through and including 215, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

216. Merck denies each and every allegation of Paragraph 216.

217. Merck denies each and every allegation of Paragraph 217.

218. Merck denies each and every allegation of Paragraph 218.

219. Merck denies each and every allegation of Paragraph 219.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

220. Merck repleads its answers to Paragraphs 1 through and including 219, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

221. Merck denies each and every allegation of Paragraph 221.

222. Merck denies each and every allegation of Paragraph 222.

223. Merck denies each and every allegation of Paragraph 223.

224. Merck denies each and every allegation of Paragraph 224.

225. Merck denies each and every allegation of Paragraph 225.

226. Merck denies each and every allegation of Paragraph 226.

EIGHTH CAUSE OF ACTION

FRAUD

227. Merck repleads its answers to Paragraphs 1 through and including 226, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

228. Merck denies each and every allegation of Paragraph 228.

229. Merck denies each and every allegation of Paragraph 229.

230. Merck denies each and every allegation of Paragraph 230.

231. Merck denies each and every allegation of Paragraph 231.

232. Merck denies each and every allegation of Paragraph 232.

233. Merck denies each and every allegation of Paragraph 233.

234. Merck denies each and every allegation of Paragraph 234.

235. Merck denies each and every allegation of Paragraph 235.

236. Merck denies each and every allegation of Paragraph 236.

237. Merck denies each and every allegation of Paragraph 237.

238. Merck denies each and every allegation of Paragraph 238.

239. Merck denies each and every allegation of Paragraph 239.

240. Merck denies each and every allegation of Paragraph 240.

NINTH CAUSE OF ACTION**VIOLATION OF BUSINESS & PROFESSIONS CODE § 17200**

241. Merck repleads its answers to Paragraphs 1 through and including 240, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

242. Merck admits that Plaintiff purports to bring a civil action for damages, but denies that there is any legal or factual basis for same. Merck denies the remaining allegations of Paragraph 242.

243. The allegations in Paragraph 243 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

244. Merck denies each and every allegation of Paragraph 244, including each and every allegation of subparagraphs (a) through (d).

245. Merck denies each and every allegation of Paragraph 245.

246. Merck denies each and every allegation of Paragraph 246.

247. Merck denies each and every allegation of Paragraph 247.

248. Merck denies each and every allegation of Paragraph 248.

249. Merck denies each and every allegation of Paragraph 249.

TENTH CAUSE OF ACTION**VIOLATION OF BUSINESS & PROFESSIONS CODE § 17500**

250. Merck repleads its answers to Paragraphs 1 through and including 249, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

251. Merck admits that Plaintiff purports to bring a civil action for damages, but denies that there is any legal or factual basis for same. Merck denies the remaining allegations of Paragraph 251.

252. The allegations of Paragraph 252 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

253. Merck denies each and every allegation of Paragraph 253, including each and every allegation of subparagraphs (a) through (d).

254. Merck denies each and every allegation of Paragraph 254.

255. Merck denies each and every allegation of Paragraph 255.

256. Merck denies each and every allegation of Paragraph 256.

257. Merck denies each and every allegation of Paragraph 257.

258. Merck denies each and every allegation of Paragraph 258.

ELEVENTH CAUSE OF ACTION

VIOLATION OF CIVIL CODE §§ 1750 ET. SEQ.

259. Merck repleads its answers to Paragraphs 1 through and including 258, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

260. Merck denies each and every allegation of Paragraph 260.

261. Merck admits that Plaintiff purports to bring a civil action and seeks injunctive relief, but denies that there is any legal or factual basis for same. Merck denies the remaining allegations of Paragraph 261.

262. The allegations of Paragraph 262 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

263. Merck denies each and every allegation of Paragraph 263.

264. Merck denies each and every allegation of the Paragraph 264, including each and every allegation of subparagraphs (a) through (d).

265. Merck denies each and every allegation of Paragraph 265.

266. Merck denies each and every allegation of Paragraph 266.

267. Merck denies each and every allegation of Paragraph 267.

RELIEF REQUESTED

WHEREFORE, Merck denies that Plaintiff is entitled to any of the requested relief, including Paragraphs (1) through (12), and respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert affirmative defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiff's Complaint that Merck has not expressly admitted. Further answering and by way of affirmative defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff is barred from recovering against Merck because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by applicable federal law, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to its prescribing physician. To the extent that New Jersey law is found to apply to Plaintiff's claims, Plaintiff's claims are barred because Merck has discharged its duty to warn under N.J.S.A. 2A:58C-4 in its warning to prescribing physicians.

SEVENTH AFFIRMATIVE DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned or reduced in accordance with the applicable law.

EIGHTH AFFIRMATIVE DEFENSE

The injuries and damages, if any, sustained by Plaintiff resulted in whole or in part from her own contributory or comparative negligence and any damages recovered should be reduced and/or barred in accordance with the applicable law.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claims are barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to prevent or mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States of America and the Constitutions of the State of New Jersey, the State of North Carolina, and the State of California.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was manufactured and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating prescription drugs, including FOSAMAX®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

FORTIETH AFFIRMATIVE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

FORTY-FIRST AFFIRMATIVE DEFENSE

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiff.

FORTY-SECOND AFFIRMATIVE DEFENSE

To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

FORTY-THIRD AFFIRMATIVE DEFENSE

To the extent that New Jersey law applies to Plaintiff's claims and to the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any source for injuries in the Complaint, such benefits are not recoverable in this action under N.J.S.A. 2A:15-97.

FORTY-FOURTH AFFIRMATIVE DEFENSE

The defendant is not guilty of negligence and violated no duty owing to Plaintiff.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks capacity and/or standing to bring such claims.

FORTY-SIXTH AFFIRMATIVE DEFENSE

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrine of accord and satisfaction, res judicata, payment and/or release.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's damages are barred or reduced by the doctrine of avoidable consequences.

FORTY-NINTH AFFIRMATIVE DEFENSE

With respect to Plaintiff's demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003); Philip Morris USA v. Williams, 549 U.S. 346 (2007), and Exxon Shipping Co. v. Baker, 128 S. Ct. 2605 (2008).

FIFTIETH AFFIRMATIVE DEFENSE

To the extent that Plaintiff attempts to seek equitable relief, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

FIFTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff is barred from recovery and/or Plaintiff's recovery is limited pursuant to the Comparative Negligence Act, N.J.S.A. 2A:15-5.1, et seq. to the extent that New Jersey law applies to Plaintiff's claims.

FIFTY-SECOND AFFIRMATIVE DEFENSE

Merck denies any liability on its part, but if Merck is ultimately found liable to Plaintiff, then it shall only be liable for its equitable share of Plaintiff's recovery since any liability which would be found against it will be insufficient to impose joint liability. In the alternative, the liability, if any, of Merck is limited by and pursuant to the New Jersey Joint Tortfeasor Contribution Act, N.J.S.A. 2A:53A-1, et seq. to the extent that New Jersey law applies to Plaintiff's claims.

FIFTY-THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel or waiver.

FIFTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that New Jersey law applies to Plaintiff's claims, Merck asserts all defenses available to it pursuant to N.J.S.A. 2A:58C-1, et seq., otherwise known as the New Jersey Product Liability Act.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

To the extent that New Jersey law applies to Plaintiff's claims, those claims are confined to those available under the New Jersey Product Liability Act.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

Venue in this case may be improper.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of forum non conveniens.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE

To the extent the Court finds that any of Plaintiff's claims are governed by the law of a state other than New Jersey, Merck asserts all affirmative defenses available to it under that other state's law.

FIFTY-NINTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of answering defendant, no act or omission was oppressive, fraudulent, or malicious, under California Civil Code Section 3294, and therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code Section 3294(b).

SIXTIETH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injury or loss as alleged in the Complaint, such injury or loss may have been caused by parties other than answering defendant, or third persons not parties to this action, who may have been negligent, legally responsible, or otherwise at fault. In the event of a finding of liability in favor of Plaintiff, a settlement, or a judgment against answering defendant, answering defendant requests an apportionment of fault among all parties and third persons as permitted by *Li v. Yellow Cab Company*, 532 P.2d 1226 (1975) and *America Motorcycle Association v. Superior Court*, 578 P.2d 899 (1978). Answering defendant also requests a judgment and declaration of partial indemnification and contribution against all other parties or third persons in accordance with the apportionment of fault.

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1 In so much as the Complaint does not describe the alleged underlying claims with
 2 sufficient particularity to enable Merck to determine all of its legal, contractual and
 3 equitable rights, Merck reserves the right to amend and/or supplement the averments of
 4 its Answer to assert any and all pertinent liability defenses ascertained through further
 5 investigation and discovery.

6 Merck will rely on all defenses that may become available during discovery or
 7 trial.

8 WHEREFORE, Merck respectfully demands judgment dismissing the Complaint
 9 with prejudice and awarding Merck its reasonable costs and disbursements, including
 10 reasonable attorneys' fees as may be available by law, together with such and other and
 11 further relief that the Court may deem just and proper.

12 **PRAYER FOR RELIEF**

13 WHEREFORE, Merck prays as follows:

- 14 1. That Plaintiff take nothing by the Complaint;
- 15 2. That this action be dismissed with prejudice;
- 16 3. That Merck be awarded its costs of suit herein, and its attorney's fees to
 17 the extent provided for by statute or contract;
- 18 4. For such other and further relief as the Court deems just and proper.

20 Dated: September 16, 2013

VENABLE LLP

21 By: /s/ Ben D. Whitwell

22 Ben D. Whitwell

23 Deborah A. Feinblum

24 Attorneys for Defendant

25 MERCK SHARP & DOHME CORP.

DEMAND FOR JURY TRIAL

Merck demands a trial by jury as to all issues so triable.

Dated: September 16, 2013

VENABLE LLP

By: /s/ Ben D. Whitwell
Ben D. Whitwell
Deborah A. Feinblum
Attorneys for Defendant
MERCK SHARP & DOHME CORP.

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LOS ANGELES, CA 90067
310-229-9900

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 2049 Century Park East, #2100, Los Angeles, California 90067.

On September 16, 2013, I served the foregoing document(s) described as **DEFENDANT MERCK SHARP & DOHME CORP.'S ANSWER TO COMPLAINT; DEMAND FOR JURY TRIAL** on the interested parties in this action addressed as follows:

SEE ATTACHED SERVICE LIST

☒ By placing true copies thereof enclosed in a sealed envelope(s) addressed as stated above.

☐ **BY PERSONAL SERVICE (CCP §1011):** I delivered such envelope(s) by hand to the addressee(s) as stated above.

☒ **BY MAIL (CCP §1013(a)&(b)):** I am readily familiar with the firm's practice of collection and processing correspondence for mailing with the U.S. Postal Service. Under that practice such envelope(s) is deposited with the U.S. postal service on the same day this declaration was executed, with postage thereon fully prepaid at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY (CCP §1013(c)&(d)):** I am readily familiar with the firm's practice of collection and processing items for delivery with Overnight Delivery. Under that practice such envelope(s) is deposited at a facility regularly maintained by Overnight Delivery or delivered to an authorized courier or driver authorized by Overnight Delivery to receive such envelope(s), on the same day this declaration was executed, with delivery fees fully provided for at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

Executed on September 16, 2013, at Los Angeles, California

☒ **(FEDERAL)** I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.


Jan Contreras

ATTACHED SERVICE LIST

Plaintiff In Pro Per

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